



NATIONAL ACTION PLAN ON BREAST CANCER
A Public/Private Partnership

**MEDICAL IONIZING RADIATION AND HUMAN BREAST CANCER:
ETIOLOGY WORKING GROUP**

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cancers, and the breast is particularly susceptible to damage from ionizing radiation. The but the accumulation of low doses may put a person at high risk. No “acceptable” levels sources. While many of these sources can not be modified at this time, the medical use of estimated that a threefold reduction of dose from diagnostic radiology is technologically *Reducing the quantity and improving the quality of against breast cancer.*

Workshop on Medical Ionizing Radiation

To develop recommendations for an appropriate national response regarding the effects of (NAPBC), a public/private partnership formed to stimulate rapid progress in eradicating breast Cancer. The workshop, which was held November 17 and 18, 1997, in Washington, DC, was co-the National Cancer Institute’s Radiation Epidemiology Branch, Division of Cancer Epidemiology

Participants discussed research on IR and breast cancer and what is known and/or suspected included an overview of breast cancer epidemiology, the epidemiology of radiation-related breast

research, radiation protection in medical radiography and breast cancer, the experience of the Food and Drug Administration with the Mammography Quality Standards Act (MQSA), legal issues, and concerns about issues such as medical and consumer education, responsible informed consent, and reducing ionizing radiation exposure. After each presentation, participants had the opportunity to ask questions. The workshop also included two general discussion sessions and a concluding roundtable discussion in which participants developed recommendations for future research, education, and policy.

This report is based on information presented and issues raised at the workshop. Advocates who made presentations at the workshop have identified topics of particular interest and urgency to the advocacy community with the hope that others will join them in working to reduce the risk of breast cancer from medical ionizing radiation. They also have developed through consensus recommendations for future action. *Advocates of breast cancer prevention **must** be involved in all phases of the processes described below.*

ISSUES

From an advocate's perspective, two main issues should be considered in addressing medical ionizing radiation: (1) Radiation from medical x-rays is, to some degree, excessive and may therefore contribute to breast cancer risk and the risk of breast cancer recurrence. Any unnecessary medical radiation dose should be reduced and, where possible, eliminated; and (2) The involvement of advocates should be an underlying principle in considering and implementing issue #1.

OBJECTIVES

Advocates who attended the workshop identified several major objectives in breast cancer prevention (see details for each under Recommendations):

1. Identify methods to decrease the dosage from medical x-rays and other radiologic procedures without compromising medical care.
2. Improve education for both medical personnel and consumers about the risks and benefits of medical ionizing radiation.
3. Develop guidelines for individual and cumulative exposure and methods to monitor and record exposures.
4. Increase risk reduction research in the field by manufacturers and scientists.
5. Increase public awareness of legal, ethical, and policy issues related to medical ionizing radiation and breast cancer.

6. Implement policies to help reduce the risk of breast cancer from medical ionizing radiation.

RECOMMENDATIONS

The following recommendations were developed as guidance for implementing the above objectives. (Some overlap exists among the categories.)

In all areas, strategies for achieving the objectives should be planned and implemented collegially among advocates and other pertinent groups (e.g., medical personnel, researchers, legislators).

1. Identify methods to decrease the dosage from medical x-rays and other radiologic procedures without compromising medical care.

Radiation causes cancer—including breast cancer. Therefore, reducing radiation exposure is an essential prevention strategy. *Specific strategies to achieve this objective include the following:*

- To arrive at a prudent use of x-rays and other radiologic procedures, reduce the amount of exposure at each x-ray and procedure and the number of x-rays and procedures to which people are exposed.
- Keeping in mind that sensitivity to ionizing radiation begins in utero, distinguish between absolutely necessary x-rays and those that may be useful but are nonessential. Establishing these distinctions will enhance appropriate risk assessment by both physicians and consumers.
- Determine what constitutes acceptable standards of exposure and minimally effective doses; currently, standards of exposure permit higher levels for workers in the field than for patients.
- Methods should be developed to monitor the individual and cumulative exposure and to keep records on cumulative exposure.
- Doses should be measured, not estimated; currently, the radiation dose varies from one machine to another.

2. Improve education for both medical personnel and consumers about the risks and benefits of medical ionizing radiation.

Education of medical personnel and consumers is a critical foundation for prevention efforts. Understandably, there is some overlap in the general education needs of these groups (for example, both parents and pediatricians should be educated about the dangers of IR to children). However, the specific topics, the level of detail, the medium, and even the literacy level must be

tailored to each group and to populations within these groups. Suggestions for educational publications include a fact sheet and a pamphlet for consumers and a dose booklet for medical personnel.

Education for medical personnel

A wide variety of medical personnel should be targeted for education about medical ionizing radiation because they are directly involved in administering IR, educate others on the use of IR, or routinely order x-rays for patients. These personnel include medical school deans, medical students, hospital administrators, radiation technologists, nurses, physicians, osteopaths, nurse practitioners, physician assistants, and chiropractors. Among the topics that should be encompassed in education efforts are the following:

- Risk assessment (how to determine the risks and benefits of radiation).
- The concepts of carcinogenesis, cancer models, and DNA damage.
- The effects of single and cumulative radiation exposure through the life span, starting in utero and including age-related sensitivity.
- Groups at high risk for breast cancer and/or who are highly sensitive to radiation.
- For women with breast cancer having radiation treatment and subsequent mammograms, sensitivity of the other breast.
- The need for the use of shields for patients.
- The importance of knowing what dose is given at each exposure.
- Understanding the difference between medical IR exposure and background levels of radiation and airplane travel exposure.

Other issues that medical personnel should consider include the need to track all diagnostic and treatment x-rays, including gastrointestinal (GI) studies—not just mammography—and the need to develop an easily understandable informed consent form for medical radiation exposure. In addition, certification requirements and continuing education requirements relative to radiation exposure should be developed for all medical personnel.

Consumer education

In order for consumers to be effectively involved in making decisions about their health care, it is essential for them to be educated about numerous aspects of medical ionizing radiation. A

pamphlet about the risks and benefits of medical ionizing radiation would be one useful educational medium. Recommended topics include the following:

- The issue of informed consent for radiologic procedures.
- The fact that risks are cumulative throughout the life span, and therefore exposures should be tracked.
- The need to know the exposure levels of various radiologic procedures in order to make an informed decision about treatment and diagnosis.
- Information about sensitive populations (such as individuals with ataxia telangiectasia [AT] gene mutations and breast cancer patients).
- Information about digital mammography. Although this technology has the potential for lower dose, because it is more user-friendly, it can result in more images being taken and therefore contribute to higher cumulative dose.
- The available diagnosis and treatment options for medical procedures that involve IR. Target audiences should include parents and high school students.
- Information on basic scientific topics, including cellular changes caused by ionizing radiation, why ionizing radiation is an invasive medical procedure, and the distinction between ultraviolet and ionizing radiation.
- A summary of what is known—and suspected—about medical ionizing radiation.
- Understanding the difference between medical IR exposure and background levels of radiation and airplane travel exposure.

Educational materials for consumers also could include a list of possible questions to ask health care practitioners about radiologic procedures, including the possibility of receiving nonionizing radiation. In addition, a diagram of the body with sensitive areas highlighted might be a helpful graphic aid.

3. Develop guidelines for individual and cumulative exposure and methods to monitor and record exposures.

Standards for mammography have been established through the Mammography Quality Standards Act (MQSA), under which U.S. mammography facilities are accredited and inspected by the Food and Drug Administration. The International Commission on Radiologic Protection addresses how radiation protection should be applied in medicine. However, the Federal government,

professional associations, and advocates need to help develop additional standards and related measures in several areas, including the following:

- An overview of what methods can offer protection against unnecessary exposure (e.g, physical protection, limiting the frequency and level of dose, procedural guidelines, guidelines for determining risks versus benefits of radiologic procedures).
- Standards specifically targeted to patients at high risk from radiation exposure (including AT and breast cancer patients).
- Standards regarding the frequency and the acceptable range of dose that can be administered (with the goal of using the lowest possible dose without losing film quality and therefore the diagnostic value of x-rays).
- Standards for cumulative exposures and recordkeeping systems to track radiation exposure. The tracking systems could include “smart cards” to store electronic records of exposure or improved record systems in physicians’ offices.
- Standards for the continuing education of medical personnel and for the certification of personnel, including physicians who have radiation equipment in their offices.

4. Increase risk reduction research in the field by manufacturers and scientists.

Research gaps remain in a variety of areas related to medical ionizing radiation and breast cancer. They include research on improving radiologic and other diagnostic and treatment technology, examining the effect of radiation exposure on different populations and with varying interactions, and further exploring the biological effects of radiation. Advocates should be involved in all phases of the research process, including initiating and developing research proposals.

Research by manufacturers

Manufacturers of radiologic equipment can make important contributions to the prevention of breast cancer related to radiation. For example, substantial reduction in doses from fluoroscopy and mammography have been achieved. Furthermore, such reductions have been demonstrated in radiology facilities (Gofman and O’Connor, 1985; Johns and Cunningham, 1983; Taylor et al., 1979). According to one expert, an estimated threefold reduction of dose from diagnostic radiology is technologically feasible (Taylor et al., 1979). Advocates, manufacturers, and scientists collaboratively should identify specific research and technology to reduce radiation emissions. Other recommended actions include the following:

- Encourage the development of other diagnostic tools.

- Develop devices that are easy to use and that accurately demonstrate the IR dose being emitted (e.g., meters on fluoroscopy equipment).
- Develop a “smart card” that can be used to record patients’ exposures to radiation.

Clinical research

Clinical trials, followup studies, and other research are needed in a variety of areas to add to our knowledge of the relation between IR and breast cancer. Some specific areas are listed below:

- Studies to determine what constitutes diagnostically necessary exposure.
- A retrospective study of past IR exposures in women age 50 (the age at which breast cancer becomes common) and other studies of cumulative risk data. These could facilitate developing guidelines for ceilings on cumulative exposures.
- A followup study of post-treatment patients for all diseases and conditions that involve the therapeutic use of x-rays.
- Studies of IR/drug interactions and of IR/environment interactions.
- Followup studies of newborns in the Intensive Care Unit who have undergone radiologic procedures.
- Followup studies of patients who have undergone heart catheterization and GI series.
- Occupational exposure studies (e.g., studies of radiation technologists, teachers, nurses).
- A comparative study to determine the lowest reasonable mean-glandular breast-dose for various nonmammographic examinations that involve radiation of part of the breast. Researchers would investigate one nonmammographic examination at a time and establish the corresponding entrance doses, eventually developing a protocol for each examination that would produce maximum efficacy with minimum breast-dose. Appropriate funding should be secured for the project to support contracts with researchers at radiology departments at several medical schools.
- A workshop on the interplay of genetic susceptibility to breast cancer and radiation exposure (e.g., the frequency of AT heterozygotes in breast cancer cases versus controls, relative risk of late-onset disease following radiation exposure in women from high-risk families versus the general population, and the development of laboratory assays to identify individuals with heightened sensitivity to radiation).

- For breast cancer patients, a study of the effectiveness of clinical exams versus mammography both pre- and post-diagnosis.

In addition, research should be conducted to gain more information on the realities of radiologic practice. Radiologists should be surveyed to determine what procedures currently are in effect and what can be improved. For example, a survey could try to determine how much variation exists in the level of compliance with standards of practice.

Laboratory research

Additional laboratory research is needed in new areas and to further examine areas that have suggestive but inconclusive findings. Examples include:

- Animal and molecular studies of cancer induction through IR exposure.
- Radiation-induced mutations.
- Identify new groups at high risk of breast cancer from IR exposure.
- Develop a test to identify AT heterozygous individuals (individuals who have one copy of the AT gene, as opposed to AT homozygotes, who have two copies of the gene and exhibit a multisystem disorder that includes not only extreme radiation sensitivity but also neurological disease and immunological problems). AT heterozygous individuals do not have the AT disease but have a fourfold excess breast cancer risk.
- Develop methods to determine cumulative lifetime IR exposure.

5. Increase public awareness of legal, ethical, and policy issues related to medical ionizing radiation and breast cancer.

Clinicians, providers, and the public should be aware of legislation and regulations that could either help or hinder the reduction of IR exposure. These issues fall into several categories, as outlined below.

Regulation

- If a goal is to regulate exposure to medical ionizing radiation, the purpose of the regulation should be determined (e.g., education, guidance, accountability).
- The purpose of the regulation should determine what regulatory mechanism is most appropriate (e.g., statute, government regulation, professional standards).

- The target of the regulation, or the group who will be held accountable, must be determined (e.g., dentists, radiologists, all medical professionals).
- Compliance measures, procedures, and penalties must be determined.

Consumer rights

- Disclosure of risks associated with IR may not be sufficient protection for consumers. In addition, questions of who discloses the risks, what is disclosed, as well as how and when information is conveyed need to be addressed.
- Whether informed consent should be a requirement for IR exposure (and if so, what it would entail) needs to be determined.
- When considering lifelong or long-term records of IR exposure, issues of confidentiality and privacy need to be addressed.

Liability

- Issues such as who could be liable for negative consequences of cumulative exposure need to be considered.
- Providers' concerns about liability should be addressed; they may feel squeezed between potential allegations of malpractice for not ordering a specific radiologic procedure and possible liability for negative consequences of overexposure.

6. Implement policies to help reduce the risk of breast cancer from medical ionizing radiation.

Advocates, researchers, and legislators need to be aware of policy issues related to radiation and to collaborate on implementing policy changes to reduce the risk from IR. Important policy initiatives include the following:

- Enact Federal legislation for fluoroscopy certification (as has been done in California and other states)
- Increase the number of researchers, educators, policymakers, and others involved in radiation protection.
- Reauthorize the MQSA and ensure that funds are appropriated for its operations.

- Control the disposal of medical radiation wastes.

Reducing the quantity and improving the quality of medical x-rays and other radiologic procedures is a step that can be taken in the fight against breast cancer.

APPENDIX

MEDICAL PROCEDURES INVOLVING IONIZING RADIATION

(from Gofman and O'Connor, 1985, and Dana-Farber Cancer Institute, 1996)

The following is a list of medical procedures that involve exposure to ionizing radiation. Each of these procedures should be examined to understand its risks and benefits, and whether its results can be achieved with lower exposure. For example, the ionizing radiation used for mammographies has been reduced approximately a hundredfold in the last few decades without compromising quality of care. In the 1960s, the average dose was approximately 20 rads, whereas doses for one exam today are often as low as 0.2 rad (Gofman and O'Connor, 1985).

Abdomen*
Ankle including Foot*
Angiographies:
 Angiocardiography
 Celiac Angiography
 Cerebral Angiography
 Pulmonary Arteriography
 Renal Angiography
 Digital Subtraction and Other
Barium Enema
Barium Swallow, Wide
Barium Swallow, Narrow
Bladder (see Cystogram)
Cardiac Series, Pediatric
Cardio-angiography (or angiocardiography)
C.A.T. Scans:
 Isolated Slice Tables
 Example, Single Slice Exam
 Example, Multi-Slice Exam
Cervical Spine*
Chest*
Cholecystogram
Cystogram-Urethrogram
Dental, Single Film
Dental, Full Mouth
Elbow*
Fallopian Tubes (see Hysterosalpingography)
Femur (upper leg)*
Fluoroscopy, Nine Areas of Torso
Forearm (lower arm)*
Full Spine, Chiropractic
Gallbladder (see Cholecystogram)
Hand (see Wrist)*
Hip*
Humerus (upper arm)*

Hysterosalpingography
Interventional Cardiac Radiology
In-Utero Irradiation
I.V.P. (Intravenous Pyelogram)
Knee*
K.U.B. (Kidney-Ureter-Bladder)
Lower Arm (see Forearm)
Lower Leg (tibia and fibula)*
Lumbar Spine, Narrow*
Lumbar Spine, Wide*
Lumbo-Sacral Spine*
Mammography:
 Screening and Diagnostic Mammography
 X-Ray Guided Breast Biopsies
 Scinti-Mammography
 Computed Tomography (CT scans)
Neck*
Nuclear Medicine
 Bone Scan
 Flow Study
 Gallium Scan
 Hepatobiliary Scan
 Internal Mammary Lymphoscintigram
 Lymphoscintigram
 Oncoscint Scan
 Radionuclide Ventriculogram (RVG)
 Renal Scan
 Somatostatin Receptor Imaging Scan
 Strontium-89 Therapy
 Thallium Scan
Pelvis and Pelvimetry
Retrograde Pyelogram
Ribs*
Salpingography
Scapula*

*X-Rays

Scoliosis (monitored with repeated x-rays)
Shoulder*
Skull*
Small Bowel Series
Thoracic Spine, Wide*
Thoracic Spine, Narrow
Thoracic Spine, Special
Upper Arm*
Upper Gastro-Intestinal Series
Upper Spine*
Wrist including Hand
X-Ray Examinations in Neonatal Intensive Care
Units*

*X-Rays

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